Update on ASTHO/CSTE/NACCHO/APHL Conf Calls (questions through Jan. 29, 2003)

Centers for Disease Control and Prevention

Frequently Asked Questions supporting the National Smallpox Vaccination Program – To be posted on Member-only websites of ASTHO, NACCHO, CSTE, and APHL

Current as of February 4, 2003

Vaccine:

Are people who have never been vaccinated against smallpox excluded from Stage 1 vaccination? (1/15/03)
No.

Is the statement on the use of the bifurcated needle on the CDC Web site?
Yes. It is on the smallpox Web site.

What should be done with a spilled open vial?
The spill should be cleaned with a "tuberculocidal" agent, and the contaminated cleaning material disposed as infectious waste.

Will the number of doses of vaccine we receive for stage one take into account re-vaccination for those whose first vaccination does not result in a take?
The number of doses sent is based on state estimates of need, modified to some extent by CDC review, and should take into account the need for revaccination (estimated at 5% or less of vaccinees).

Why is the IND consent protocol being used for a licensed vaccine?
IND consent protocol is not being used for the licensed vaccine. We are making allowances for a signature to be obtained on the medical history form as most authorities still obtain consent signatures even when administering licensed vaccines. If the IND consent protocol were being used, there would be a separate consent form that contained the specific information elements required for IND consent based on Federal regulations.

Contraindications:

Question 12 on Page 4 of the Pre-Vaccination Information Packet talks about taking steroids within the past month, but other resources refer to 3 months of steroids. (1/24/03)
Potential vaccinees that have had chemotherapy or radiology during the past three months should not be vaccinated. For patient taking oral steroids in immunosuppressive doses, they are contraindicated unless they have been off steroids for greater than or equal to 1 month.

Have the contraindications for vaccination been approved? (1/22/03)
Yes. Persons in households with children under 1 may get vaccinated.

Is there any difference between the contraindications in the 1960s/1970s and today? *(1/15/03)*
The contraindications were the same except for the addition of HIV/AIDS. (Breastfeeding was not identified as contraindication in the 1960/1970s according to Fenner's text, Book 1).

Is recent PRA or eye surgery a contraindication? *(01/17/03)*
ACIP Guidelines say that persons receiving ocular steroids should not be vaccinated until therapy is completed.

Should people with contraindications inspect sites? *(1/15/03)*
No

ACIP's autoimmune recommendation could include people with minimal problems. Are these individuals contraindicated for vaccination? *(1/15/03)*
ACIP statement refers to "clinically severe". The focus is on severe cases. In a pre-event scenario, err on the side of caution, and when in doubt, exclude person from vaccination, or have them consult with their physician.

Can those people under age 30 be vaccinated? (Based on training checklist, vaccinator trainers are under the impression that no one under 30 should be vaccinated. This is based on an ACIP statement that, when feasible, people that have been previously vaccinated should be vaccinated first. Does this preclude all people under the age of 30 altogether?) *(1/15/03)*
While it is preferable to start your vaccination program with those people who have been previously vaccinated, it was certainly not intended to exclude those people under the age of 30.

Do 'Autoimmune' diseases include asplenia or stem cell transplant patients? *(1/15/03)*
Asplenia: This depends on the current state of the patient's recovery and treatment, and the reason for spleen removal. If no severe conditions or side effects are present, than this condition is not inherently a contraindication.

Stem cell transplants: Persons with hematopoietic stem cell transplants are contraindicated if<24 months post-transplant or >24 months post-transplant but who have graft-versus-host disease or disease relapse. [Refer to the Vaccina (Smallpox) Vaccine (6-22-2001) ACIP Recommendations.]

Is severe diabetes a contraindication? *(1/15/03)*
No (but if having severe symptoms, potential vaccinee should discuss this with their health care provider).

What criteria or tests should be used to know for sure that this history is accurate and that the health care worker is immune and does not need vaccine? *(1/15/03)*
A health/veterinary care worker would have to have written documentation of vaccination within 10 years (from current program date).

Can vaccinated mothers pump breast milk and have someone else feed the milk to the infant (or is the milk itself affected?)
Smallpox vaccine is not recommended for use with breast-feeding mothers during non-emergency situations.

Is rosacea a contraindication to smallpox vaccination?
Severe inflammatory acne rosacea falls into the category of an exfoliative skin condition. Therefore a patient with severe inflammatory acne rosacea may only be vaccinated when their skin condition is resolved and there is no evidence of disrupted dermis. However, the typical telangectatic rosacea or mild acne rosacea is NOT considered to be an exfoliative skin condition and therefore the individual may be vaccinated even in the presence of the rash.

How long would an individual need to wait after completing a course of oral Prednisone (e.g., 20mg) to receive smallpox vaccine?
If the dose of steroids has been given long enough to cause significant immune suppression, "Vaccination providers should wait = 1 month after discontinuation of therapy before administering a live-virus vaccine to patients who have received high systematically absorbed doses of corticosteroids for = 2 weeks" (per the Advisory Committee on Immunization Practices general recommendations on immunization).

Is it possible for pets and farm animals to get smallpox vaccinia virus (smallpox vaccine infection) from humans who have been vaccinated for smallpox?
In the case of domestic animals (pets), we are not aware of any documented cases of cats or dogs acquiring vaccinia virus from humans vaccinated for smallpox using the vaccinia virus vaccine. However, given the range of animals that can be infected with vaccinia virus we can assume they could be infected. Vaccinia virus is transmitted by direct contact with infected material, e.g. the vaccination site, hands contaminated from the vaccination site, bandages from the vaccination, etc. Proper handling of the vaccine site (covering the vaccination site with a bandage and wearing long clothing over the bandage) and good hand hygiene will prevent secondary transmission among human household members and is also sufficient to prevent transmission of vaccine vaccinia virus to household pets. To avoid transmission to a pet:

- Do not let animals sniff or have direct contact with the vaccination site or the bandages, clothing, sheets, etc that have been in direct contact with the scab.
- Keep pets out of the room when you are changing bandages or changing clothes
- Before allowing your pet back in the room after you have changed your bandage, place the bandage in a sealable plastic bag before disposal into the trash. Put any clothing that had contact with your scab in the laundry and wash your hands well after touching the site or dressing

- Make sure that pets and other animals do not have access to trash containers that have bandages in them

In the case of farm animals, the risk is also low if the vaccination site is properly handled and good hygiene is practiced. The risk to milking cows is likewise low because the dairy industry is highly automated and cows are milked by machine. If there is a concern about proper care of the vaccination site or proper hand hygiene, then recently vaccinated humans need to avoid milking cows until their scab is detached.

Do we need to screen for thimerosal allergy since it is in VIG (Vaccine Immune Globulin)?
Screening is not recommended at this time. We anticipate that at most, only a few hundred people per million vaccinated may receive VIG.

Is an urticarial rash that develops after a previous smallpox vaccination a contraindication to subsequent smallpox vaccine?
Urticarial rashes are common and the majorities are acute and self-limiting. Often the urticaria is a manifestation of an allergic IgE mediated reaction. Urticaria frequently occurs during an anaphylactic response although other signs that would be present include flushing, hypotension, syncope, respiratory blockage and abdominal symptoms. The onset of an anaphylactic response typically occurs rapidly usually within 15-30 minutes after exposure to the allergen and almost always within 24 hours. Cutaneous findings usually clear within 24 hours.
Persons with a history of urticaria but no other sign of anaphylaxis after a previous smallpox vaccination could probably be re-vaccinated without severe consequences. If there are questions or concerns about the history or the risks vs the benefits of vaccination in a pre-event setting, a referral to an allergist may be prudent**.**

Is a history of erythema multiforme after a previous smallpox vaccination a contraindication to a re-vaccination?
Erythema multiforme (EM) reactions can be both mild and self limited (EM minor) or they can be severe and progress to Stevens Johnson Syndrome (EM major). EM minor is more commonly associated with viral infections, whereas drug induced EM are more likely to become severe.
As with urticaria, the probability that a person can be safely re-vaccinated may depend on the past history of disease severity and whether the initiating allergen was a drug within the vaccine or the vaccinia virus. If there are questions or concerns about the history or the risks vs. the benefits of vaccination in a pre-event setting, a referral may be prudent.

Should persons with a history of latex allergy be advised not to volunteer? *(01/10/2003)*
The package insert notes in the Precautions section that the vial contains dry, natural rubber and may cause a hypersensitivity reaction when administered to persons with known or possible latex sensitivity. The ACIP's General Recommendations for Immunization advises that persons who have a severe (anaphylactic) allergy to latex should not be given vaccinations supplied in a vial that contains natural rubber.

However, vaccines supplied in vials or syringes with natural rubber can be administered to persons with less hypersensitivity (such as contact allergy to latex gloves).

Is chronic fatigue syndrome a contraindication for pre-event vaccination?
Persons with chronic fatigue syndrome (CFS) do not have an immunosuppression detectable in laboratory tests and CFS in itself is not a contraindication. However, persons with CFS sometimes suffer exacerbations of their symptoms following viral infections. While there are no prior data, it is possible that disease symptoms in a person with CFS could increase after smallpox vaccination. Persons with CFS may want to discuss their individual situation with their treating physician before vaccination.

Vaccination Procedures:

On the Patient Medical History and Consent Form, to what does the term "medical screener" refer? (1/29/03)
This term is based on requirements for other immunization programs. A "medical screener" is a witness; anyone can be a witness. Future revisions of this form may remove this section.

How do you designate between a "primary" versus "secondary" vaccinee? (1/29/03)
A person is determined to be a primary vaccinee based on their medical history. If they don't know or did not receive the smallpox vaccine previously, then they should be treated as a primary vaccinee. If they were born prior to 1972, they were most likely vaccinated, although this is not guaranteed. The vaccinator should err on the side of revaccination, as this requires 15 punctures, and has a higher probability of a take.

If someone doesn't check yes that they can be contacted on the Medical History and Consent form, can they be vaccinated? (1/29/03)
They cannot be vaccinated.

What if the Patient Medical History and Consent Form is not fully completed regarding some questions (e.g., race/ethnicity, SSN)—does this mean the person is disqualified from being vaccinated? (1/29/03)
A potential vaccinee must provide complete all the information on the Patient Medical History and Consent Form as part of the vaccination process. If an individual refuses to complete the information, he/she cannot be vaccinated.

What is the ACIP recommending for the number of needle sticks? (1/29/03)
On January 29, 2003, the ACIP met by conference call to finalize supplemental recommendations for use of smallpox vaccine. The Committee recommended that smallpox vaccine be given in accordance with the package insert, with 3 insertions of the bifurcated needle for primary vaccination and 15 insertions for revaccination. A trace of blood should appear at the site of vaccination within 15-20 seconds; if no trace of blood is visible, an additional 3 insertions should be made using the same bifurcated needle without reinserting the needle into the vaccine vial. (Note: Approved by Dixie, David, Kevin, and Julie)

What are the protocols on vaccination of those that will be caring for vaccinees? (1/27/03)
In terms of site care, it has been stated that these people should be vaccinated if possible. For care of adverse effects, it would be ideal for these providers to be vaccinated, but as the providers cannot be identified ahead of time, this is unrealistic. More information will be provided in MMWR, summarizing the ACIP recommendations.

How should it be verified that a person has been vaccinated previously? (1/24/03)
Definitive evidence for secondary vaccinees is a scar or a record of vaccination. Preemptive evidence is a DOB prior to 1977, or service in the military prior to 1990.

Do health workers doing vaccination site checks require vaccination? (1/22/03)
No. It is preferable that health workers doing site checks be vaccinated, but not absolutely necessary.

Is there a consent form? *(01/17/03)*
The consent form is part of the Medical History form. It can be found at website: http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/history-consent-form.pdf

Vaccine site care in hospitals. Until the papule develops, the risk of shedding is minimal since the virus is not replicating. Is this supported? *(01/17/03)*
This has not been addressed by ACIP specifically. Without viral replication on the site, the risk of transmission is very small. However, as this has not been addressed by ACIP, it is not included formally in their recommendations.

ACIP Guidelines: Dressing Changes *(01/17/03)*
For healthcare workers, daily checks of the vaccination site to assess the need for a dressing change are recommended. However, dressing changes should only be done as needed (expected once every 3-5 days).

Forms that are designed for PVS ask people if they are comfortable giving their names/information with CDC. For states not using PVS, this does not apply. Do these states need to share their changes to the forms with the CDC? *(01/17/03)*
Yes.

Do vaccinators have to have a documented take before they can begin vaccinating? Do the people that are inspecting vaccination sites and replacing dressings need to be vaccinated? How far in advance does a vaccinator need to be vaccinated prior to administering vaccine? *(1/15/03)*
If feasible, it is preferred to vaccinate the vaccinators in advance of beginning their work. However, if necessary it is acceptable for vaccinators to be vaccinated immediately prior to beginning their role as a vaccinator. While it is preferred that vaccinators be vaccinated, it is not required (ACIP discussed this issue at its fall meeting and requiring vaccinators to be vaccinated was not adopted.) For those that are regularly changing dressings and handling dressings, vaccination is recommended. For those inspecting the

dressings on an infrequent basis, vaccination is not required. The guidance refers to those in a work setting inspecting large numbers of vaccines.

Should vaccinators place a drop on the skin and vaccinate on drop? Seems to be a discrepancy between CDC and package insert. Should we tell people not to refer to the package insert? *(1/15/03)*
CDC guidance recommends vaccination without putting drop on skin. Don't tell people not to refer to the package insert.

Does ACIP recommend that the semi-permeable dressing be removed while vaccinees not at work? (1/15/03)
Semi-permeable dressing is worn in the health care setting. CDC recommends daily site inspections and dressing changes as needed, usually 3-5 days. Vaccinees do not have to come for site checks when not working.

At many hospitals, the staff uniforms are washed in the hospital laundry. Are there any precautions that hospital laundry staff need to take when washing uniforms from vaccinated staff? *(01/15/03)*
Clothing or any other material that may have come in contact with the vaccination site and therefore be contaminated with vaccinia should be handled with special care. A separate hamper should be used for these items. Contact with these items should be kept to a minimum. These items should be laundered in hot water with detergent or bleach. After handling, individuals should wash their hands thoroughly in warm water with soap.

Does re-vaccination have to occur on Day 8 when "no take" is documented, or could re-vaccination be delayed one week when the second round of vaccination takes place at a facility (for the half of employees who were not vaccinated at the first clinic in order to stagger the number of employees who might miss some work)?
Re-vaccination does not have to occur on Day 8 if responsible hospital and clinic staff can assure that the person will return on the later date for vaccination.

What if a filled needle is contaminated ? Is the liquid-filled needle placed in the biohazard container? Could it leak out?
The needle should be disposed in a sharps container. The vaccine quantity is so small that leakage should not be an issue.

What should be done if the vaccine is administered too lightly without seeing blood?
Since we aren't in an emergency situation, if vaccine is administered and no blood is seen, wait until the reading period (day 6-8) to determine if it is a no-take before readministering vaccine.

What should be done if the vaccine is administered too rigorously or deep (if that is possible)?
If you feel that you've administered the vaccine too vigorously or deep, wait to see if a take occurred on day 6-8 and revaccinate if no take occurred.

What should we do if the client becomes ill and/or faints before all punctures made?
If they faint during the administration, the vaccinator should stop the procedure and then check on day 6-8 to see if enough vaccine was administered to illicit a take (i.e., a major reaction is seen). If not, revaccinate at that time.

What should we do if the client changes his/her mind in the middle of vaccinating?
Stop the procedure.

If revaccination is needed (no take after first vaccination), should the second vaccination be administered in the opposite arm?
Not necessarily. Revaccination can be done in the same arm as the first dose.

What is CDC's strategy for the distribution of vaccine? When and how much? *(1/10/2003)*
CDC will ship up to 10,000 doses (100 vials) to each state initially and then follow-up with the remaining doses in one or more additional shipments. NPS is ready to ship the vaccine but states may have to assume liability for vaccine received before Jan 24.

When do states need to complete vaccination?
States should conduct their programs expeditiously, but never sacrifice safety for speed.

Will CDC provide a vaccination record for vaccinees?
Each state will develop their system for documenting a successful vaccination. CDC has developed a "Proof of Vaccination" form that can be stamped by the vaccinating assistant and given to the vaccine.

What are the requirements for a state to receive smallpox vaccine shipments? *(1/10/2003)*
The state's pre-event plan must be approved without any contingencies.

What is the start date of the vaccination program? *(1/10/2003)*
States will determine their own start dates based on approved plans, receipt of vaccine, and completed training and education of their vaccinators and other staff. Liability coverage against inappropriate shipping, storage or handling of vaccine under the Homeland Security Act does not take effect until the Secretary of Health and Human Services issues a declaration invoking Section 304 of the Act.

Should non-HCW response team members and/or vaccinators be allowed to choose the body site they prefer for vaccination?
Although non-HCWs may not require daily observations of their vaccination sites for the purposes of infection control, CDC encourages the states to maintain a policy that only the deltoid region of the arm be used as a vaccination site. In addition to the ease of observation and dressing changes, the deltoid region is easier to keep dry while bathing or showering. Also, the arm is more easily left uncovered or lightly bandaged during the day than the thigh, hip or back. Consequently, a site on the arm may heal more rapidly. State Health Departments also need to consider how a policy or precedent that allows

choice of site will be implemented during the next stage of vaccinations when potentially millions of emergency responders will be vaccinated.

Does the ACIP recommendation nullify the package insert regarding 3 vs 15 sticks? *(1/10/2003)*
The ACIP is consulting with Wyeth regarding the status of changing the current package insert. Wyeth is reviewing available data to determine if and how to best make a change in the recommended number of sticks. Should the ACIP recommendations differ from a package insert, then the ACIP provides the rationale for the difference.

Will CDC provide a vaccination card? *(1/10/2003)*
CDC will not provide the card but the Immunization Action Coalition (IAC) will provide a card that can be downloaded free of charge in a PDF file off of their website. In addition, actual cards can be purchased from the IAC. Information regarding downloading or purchasing cards will be available on the IAC website, www.immunize.org

When will VIS and patient information packets be sent? *(1/10/2003)*
These materials were mailed 1/18/03 to State Health Departments.

Should vaccinators wear goggles or other eye protection while administering smallpox vaccine? *(1/10/2003)*
There is no need for vaccinators to wear eye protection while administering smallpox vaccine. A vial of vaccine reconstituted 1:1 contains only 2.5 ml of diluent. In addition, the glycerol in the vaccine makes the solution viscous so that it adheres to the bifurcated needle. Both of these factors greatly decrease the chance that vaccine would splash into an eye.

How often should the vaccination site dressings on persons in health care settings be changed? *(1/10/2003)*
In CDC's original guidance, we stated that the dressing should be changed daily. However, this may not be practical or necessary. Each workday, the vaccination site of the HCW should be evaluated at the workplace before the HCW starts duties. If the site is clean and dry and the bandage has been on for <5 days, there is no need to change the dressing. If, however, there are signs that bandage is or soon will be leaking, or the HCW has concerns that the sight may be infected, or the same bandage has been on 5 or more days, then the dressing needs to be changed. To speed the healing process, HCWs should be encouraged to remove the semi-occlusive dressings on their off-days.

What is the recommended frequency for vaccinees that do not have patient care responsibilities? *(1/10/2003)*
Vaccinees who do not work in a hospital setting do not need to use a semi-permeable dressing over their vaccination site. If the site is oozing, the vaccinee can use a clean absorbent material such as gauze held in place by an adhesive strip or tape. In addition, a sleeve long enough to cover the site will also provide some protection against site

leakage. Bandages should be changed when the there are signs of impending leakage or the adhesive tapes holding the bandage become loose and may fall.

Must a grantee have their non-PVS system certified before inputting the data obtained when they vaccinated their vaccinators? *(1/10/2003)*
Yes.

Will PVS be available for testing at the state health department level? If so, when? *(1/10/2003)*
Yes. Should be ready Jan 21.

In order to test PVS, can a state use test data that will later be deleted? *(1/10/2003)*
Yes. States must supply their own data for testing. At the time smallpox vaccination is implemented a new server will be provided.

Can hospital staff enter vaccination data into PVS or must all data be input by the SHD? *(1/10/2003)*
Each state will provide to CDC the names of persons designated to input data. These designated persons can be at any location that has been defined by the State as a PVS organization.

When can a SHD begin to pre-populate the PVS? *(1/10/2003)*
CDC will do the pre-population. States will provide CDC with an Access database for recording population data. States should have the necessary information to accomplish this. PVS will be populated as soon as the information is received.

What is the progress on CDC certification of non-PVS system? *(1/10/2003)*
CDC has contracted a group of persons to do the certification. The time needed for certification is dependent on the number of certifications in progress and the states' timely participation in the process.

What data must be included in non-PVS systems? *(1/10/2003)*
The CDC certification team will contact the states using non-PVS systems and will discuss the data exchange and functionality requirements for certification. States should review Annex 7 of the state guidance document which discusses data exchange. The team obtains the information on which states and whom to contact from the state plans that have been submitted.

Can a state submit a proposal/make suggestion on data elements within PVS? *(1/10/2003)*
The data elements that uniquely define a batch number are: organization (clinic), vaccine lot number/manufacturer, diluent lot number/manufacturer, and date of reconstitution including hour and minute.
(The hour and minute may be necessary in large clinics that reconstitute more than one vial of vaccine in a day.) The batch number that will be inputted will be a sequential number that starts with "1" and is unique across all the batches within the system. The

database links the Batch number to the detailed information thus saving time during data entry.

What is the PVS Help Desk Number?
1-800-232-2522

Who should receive operational questions?
Each grantee can send operational questions to the CDC BT Project Officer or send them to their appropriate group (ASTHO/NACCHO/CSTE/APHL) and each question will be batched as Qs and sent to CDC.

Is CDC going to publish the algorithms for AE management in the MMWR? Can this information be shared? *(1/08/2003)*
The algorithms will be published in the January 24 MMWR, but the information cannot be universally shared before then.

Are AEs reported in PVS?
No. PVS will provide links to VAERS. *Comment: NYC has designed a hybrid form that allows a cross-walk from the NYF patient vaccination system to VAERS I order to upload the information to VAERS. NYC will share this form with other grantees.*

Is CDC aware that NPS is telling some grantees that they will not receive vaccine until the end of January or early February?
NPS is ready to ship vaccine anytime but is waiting on a directive from CDC prior to changing the existing date. Current directive is to ship vaccine on or after January 24. NPS will only ship on Monday, Tuesday, or Wednesday due to the need to receive the temp-tail back from the grantees before authorizing the grantees to vaccinate.

Are the forms in the PVS system up-to-date? *(1/13/2003)*
These forms were finalized on 1/14/03. They will be incorporated into Annex 3, which will be redistributed.

When will annexes pertaining to users of the non-PVS systems be updated?
(1/13/2003)
Data Management Annexes are being revised and will be reposted to the Web site.
Annex 6 – 1/15/03
Annex 7 – 1/15/03
Annex 8 – end of that week
Those states that are using their own systems will be individually contacted with these updates.

Are states required to use CDC Medical History form? *(1/13/2003)*
Medical History Form is in Annex 3 which is being updated. States not using this form should contact CDC to let them know.

What is the current recommendation on dressing changes? *(1/13/2003)*
Change dressing when pus gathers under gauze, approximately every 3-5 days. Vaccinees need to wear the semi-permeable dressing only while at work. Specific language will be included in ACIP recommendations.

Is the consent form a part of the Medical History form? *(1/13/2003)*
Yes.

When will the Patient Advice video be distributed? *(1/13/2003)*
It will be ready for distribution 1/17/03. Copies can be ordered from the Public Health Foundation. ASTHO and CDC will coordinate number of videos required by states.

Post Vaccination:
When will the final versions of the of the site check document be ready? Some hospitals are going to furlough workers and, therefore, will not be performing site checks. (1/27/03)
Site checks are voluntary if the vaccinee is not working. Hospitals are required to track the site checks and a web-based system will be available to support this activity.

Are states expected to do active surveillance for adverse events, regardless of their participation in the Kaiser survey? (1/24/03)
IOM has recommended that states do Active Surveillance for as many vaccinees as possible. As vaccinees are coming for site care, they should be assessed for serious clinical events and documented, especially up through Day 7. In addition, CDC has requested that all follow up be done with all vaccinees between Days 21 and 28.

If someone was vaccinated in the past but did not have a take, are they considered a primary or secondary vaccinee? (1/24/03)
If there was no take, they are not previously vaccinated. If there was a take, then they are a secondary vaccinee.

On the form, there are three options to read take: Major, Equivocal, and No Take. How are these different? (1/24/03)
These terms are on many of the forms. Clinicians who are reading takes should not spend a lot of time on the difference between Equivocal and No Take. Equivocal is the same as No Take. Only a Major reaction is counted as a take.

Did MMWR on smallpox vaccine adverse events and their treatment get published today? (1/24/03)
Did MMWR on smallpox vaccine adverse events and their treatment get published today?

Is 12 hours a short period of time to receive the VIG? How quickly will the serious AEs evolve? *(1/15/03)*

Twelve hours is felt to be an adequate amount of time to respond to all AEs following smallpox vaccination.

Is the immunization card given to the patient? *(1/17/03)*
Yes. The Immunization Action Coalition has the form on their web site but it is not part of the official smallpox program. (See http://www.immunize.org)

How will requests for lab analysis be handled for cases of accidental inoculations?
Requests for lab testing are being referred to the state public health laboratory director who identifies a local or state laboratory with the capability of testing for vaccinia.

What are the recommended intervals for site monitoring? *(1/06/2003)*
Daily for those who are working but others do not need to be monitored daily. Purpose is to maintain the integrity of the dressing and not the site.

Has the process of recording site monitoring been formalized? And who needs to confirm the 7 day take? *(1/06/2003)*
Last screen of PVS allows recording of site checks. Vaccination cards can be given to the patient as a record of vaccination.

What AEs is CDC interested in collecting? And are there any case definitions for these? *(1/06/2003)*
We are interested in collecting the serious cases and are working on a system to get more frequent AE data than the regular VIG treatment data. We will discuss this topic in greater detail in the stakeholder working group.

Since VAERS is a passive system, have you considered any positive systems? *(1/06/2003)*
We will be conducting active surveillance using a telephone survey of 10 thousand people at 10 and 21 day intervals and an analysis of the daily assessment of hospital workers' symptoms (sample size has not been determined).

Has the extended VAERS form been finalized? *(1/06/2003)*
The IT staff is working on the form.

How will the AEs get reported back to the states? And, how often? *(1/06/2003)*
An internal working group is reviewing this issue and will have a preliminary idea of the issues soon. *Comment: Concern about disclosure without consent.*

How soon will VIG be available once an AE is diagnosed? *(1/08/2003)*
VIG will be received within 12 hours of CDC being notified.

What is the policy for reporting a smallpox adverse event under the existing infectious disease reporting requirements? There is no present fit for this *(12/20/2002).*
Until the smallpox vaccine reporting system is established, health care providers should contact their state health department to report the adverse event and submit a report to

VAERS. If further consultation is required, the state health department should contact the CDC Clinician Information Line for assistance, 1-877-554-4625.

What is the policy, permission, or authority that is required to use VAERS as the adverse event reporting system for smallpox adverse events? *(12/20/2002)*
VAERS was established to collect reports or adverse events (AE) after vaccination with vaccines. VAERS also accepts reports for AE from any licensed vaccine.

In determining the reporting requirements for adverse events, can states amend the administrative rules currently in place? *(12/20/2002)*
As part of all bioterrorism and immunization activities, states should ensure that they have the authority to conduct all activities required to do public health activities.

How should adverse events be reported for those patients who present with an adverse event from a secondary vaccination? *(12/20/2002)*
The same procedures should be followed for reporting adverse events for vaccine recipients.

If a vaccinia adverse event is reported, who will confirm the case? *(12/20/2002)*
Health care providers should work with their state to determine the appropriate diagnosis for a possible adverse event through laboratory testing, as appropriate. If the state requires additional assistance, they can contact CDC.

What are the guidelines for use of digital cameras to record cases of adverse events? *(12/27/2002)*
Digital cameras are extremely helpful in obtaining diagnostic assistance from experts not in the same geographic area. They can also help to document unexpected adverse events. Health care providers should obtain permission to share photos with the health department and CDC and should always take steps to protect the identity of the patient. States should consult with their own legal counsel regarding the permissions required under state law.

Are Federal employees who are part of the Smallpox Response Teams and have an adverse event from the vaccine covered under worker's compensation?
Yes. Federal employees who are part of the smallpox response teams are covered by worker's compensation and are eligible for continuation of pay up to 45 days while the claim is pending.

How soon can a volunteer donate blood after being vaccinated? *(12/18/2002)*
The FDA has determined that the deferment period for donating blood after receiving a smallpox vaccination is three weeks.

Response to Vaccination:

If the CDC finds, in administering the vaccines, that a particular smallpox vaccine or vaccine lot has a larger number of Adverse Events than the other manufacturers or

lots, will the CDC suspend the use of those vaccines and utilize instead the vaccines and/or lots with fewer reactions?
CDC and FDA both play a role in monitoring the safety of any vaccine. For smallpox vaccine, both agencies will routinely examine the adverse event reports for vaccines, by lot, using VAERS data and, if necessary, proprietary information provided by the manufacturers. However, knowing the number of adverse events per lot is only useful when put into the context of lot size and how long the lot has been on the market (to estimate how much of the lot might have already been used). In the first stage of vaccination only one lot of smallpox vaccine will be used. For the second stage of vaccination, only one manufacturer's vaccine will be used. The results of adverse events, by lot, will be presented to both the Data Safety Monitoring Board (DSMB) and the Institute of Medicine (IOM) for immediate review and recommendation. CDC and FDA will consider these recommendations in all decisions regarding the safety of smallpox vaccine.

If CDC finds that a particular smallpox vaccine or vaccine lot has a larger number of Adverse Events than the other manufacturers or lots, will they make available publicly the information on which vaccine is safer? Will such a finding also impact future vaccine purchasing decisions and how?
Vaccine safety is one of the CDC's highest priorities, and information about the safety and effectiveness of the smallpox vaccines used in this program will be shared widely. Further, meetings of the advisory committees that will assist CDC in the evaluation of smallpox vaccine safety data and immunization policies- the IOM review group and the Data Safety Monitoring Board- involve public meetings, discussions, and decision making. If there is a highly suspected or confirmed causal relationship between smallpox vaccine and adverse reactions, CDC will quickly and visibly communicate its actions and recommendations to the public, media, healthcare community and others.

CDC will continue its current practice of monitoring Adverse Events and following up on signals that may indicate unusual patterns. CDC and FDA will work closely with vaccine manufacturers, health care providers and formal immunization advisory committees (i.e. ACIP, ACCV, NVAC, VRBPAC) to determine whether changes in vaccine policies are necessary. Contracts are currently in place to secure the purchase of enough vaccine to vaccinate the entire population of the United States.

Does the CDC plan to do a longer-term follow-up with some of the 10,000 to 20,000 in the active surveillance group? Will there be anything longer than a 21 day follow-up with this group, to determine if these individuals have additional longer-term Adverse Events that might not be recognizable within the first few weeks of vaccination?
Everyone who is vaccinated with smallpox vaccine will be provided with information on how they can report any adverse events through the Vaccine Adverse Events Reporting System (VAERS) and they will be encouraged to do so. These reports can be made at anytime after vaccination.

CDC plans to conduct active surveillance to rapidly identify any vaccine adverse events (VAEs) in vaccinees and/or household contacts. The goal of this activity is to rapidly

identify VAEs in vaccinees and/or household contacts and to collect, organize and analyze information from follow-up of 20,000 vaccinees/household contacts. This follow-up will result in an increased capacity to identify VAEs and appropriately refer for treatment. This survey will also assist in developing rates of common AEs, as well as assessing the impact on time lost from work and evaluating vaccinee satisfaction with the immunization program. At this point, CDC is focusing on acute adverse events since acute events have been causally related to vaccinia. It will consider longer term follow-up in the future.

Is CDC creating documentation on takes? *(1/13/2003)*
Take readings are up to the states and will be done at the local level.

Have studies been done to determine whether vaccinia is found in the nasopharynx during the viremic phase?
Studies in vaccinated children recovered vaccinia virus from tonsillar swabs 7-15 days after vaccination. Recovery of virus from the tonsils was not typical, and was more likely if the vaccinated child developed post-vaccinal tonsillitis. However, there is no evidence of droplet transmission of vaccinia virus.

Is there a viremia after vaccination?
There can be a viremia after vaccination. An early (1930) study reported detectable viremia between days 3-10 post vaccination (most often on the 6th day). The extent of viremia may be dependent on the strain of virus used in the vaccine with the NYBOH strain producing a rare, transient viremia.

Smallpox Disease:
Can generalized vaccinia be transmitted through the air? Do patients presenting with generalized vaccinia need to be placed in negative pressure rooms? When will these and other infection control issues be published? (1/27/03)
There has been some evidence of airborne transmission, but under further inspection, it was concluded that this is not a realistic threat. HICPAC will review their recommendations on 2/3/03. In general, reasonable contact awareness should be exercised for patients with generalized vaccinia. Written infection control recommendations will follow shortly.

Are there any data from the military experience with smallpox vaccinations in the 1970's and 1980's?
U.S. military use of smallpox vaccine dates back to 1812. During the 20th century, tens of millions of US Service Members were vaccinated against smallpox, routinely from World War I until 1990.

During World War II, more than 6 million Americans in uniform were vaccinated against smallpox, sometimes as often as annually. During the 1940s, most troops were revaccinated, have been vaccinated against smallpox as children. During World War II, eight cases of post-vaccinial encephalitis were recorded. One soldier was left partially blind, three died.

During the 1970s and 1980s, DOD medical authorities reported a rate of 54 serious complications (primarily hospitalizations to evaluate generalized rashes) per million smallpox vaccinations, with no deaths attributed in a cause-and-effect manner. From 1965-75, there were six recorded encephalitis cases temporally related to smallpox vaccination in the US Air Force

.

Most smallpox vaccinations administered to troops from the 1940s to 1990 were re-vaccinations.

In the event of a smallpox outbreak, before large numbers of laboratory and medical staff personnel and law enforcement officials are vaccinated, is there a plan to get vaccine quickly to these persons?

In the event of a case of smallpox, any person who risks exposure to cases or their infectious specimens would be vaccinated as quickly as possible. Affected states would use the vaccine available either on hand or through CDC to quickly vaccinate those at higher risk such as laboratory staff, health care and law enforcement workers.

If an outbreak occurs, will the National Pharmaceutical Stockpile be able to quickly ship smallpox vaccine?

The National Pharmaceutical Stockpile plans to distribute smallpox vaccine on the first day of a bioterrorism event to anyone who has been exposed. After that initial shipment, CDC will ship smallpox vaccine over the next 5-6 days to the rest of the country as needed.

Vaccination Program:

Is the medication information collected on the Patient Medical History and Consent Form tracked in the PVS system? (1/29/03)

No, these are not captured in the PVS system. States may want to capture this information on separate forms so that the data entry personnel never see it.

Where are states required to put the PVN sticker (what forms)? (1/29/03)

On the Patient Medical History and Consent Form, vaccination card, and 1 sticker should be given to the vaccinee so it can be put on the VAERS form, if that is needed later – the vaccinee needs the keep the sticker for post-vaccination follow up.

Is it required to put PVN stickers on each page of the Patient Medical History and Consent Form? (1/29/03)

There is space on the top of each page for the PVN sticker.

What is the turnaround on granting security certificates? Have the states that are currently vaccinating been approved for their security certificates? (1/29/03)

Some of these states have it set up, but not all. Several states have their certifications submitted, but have additional steps to complete the process. Then approval time can be as short as 48 hours.

Will user logins define access to the different systems? (1/29/03)
Yes, logins will limit the systems a user can access on the first page.

If a state is using their own systems in lieu of PVS, can the systems be integrated with VAERS so that clinicians' data entry burden is limited? (1/29/03)
This is unfortunately not a possibility due to federal limitations on data interfaces. Anyone can fill out a VAERS report even if the state is using their own system for PVS.

If a state has trouble using PVS when they start their vaccinations, how should they capture the necessary information and report back? (1/29/03)
PVS is only used to facilitate state's reporting of their information. An email has/will be sent with information on the bi-weekly reporting requirements (e.g., number vaccinated, number with takes, number of participating hospitals).

Will low literacy information materials be developed by CDC? (1/27/03)
Yes.

The Privacy Act statement says that all of the information on the patient screening form is voluntary. Is it truly voluntary? How does this work legally? (1/27/03)
This means vaccination is voluntary, but the provision of information is not. If a potential vaccinee refuses to provide the information requested on the form, they cannot be vaccinated.

What is the crosswalk between PVS and the Vaccinee Monitoring System for hospitals? When will surveillance be required for all vaccinees? (1/27/03)
PVS offers the entry into the system for documenting vaccination. The voluntary hospital system is provided to help hospitals monitor the employees who have been vaccinated; e.g., to record take readings, site checks, bandage changes, etc. This is being developed in response to hospitals requesting the ability to capture this information.

The other system, the Hospital Monitoring/Active Surveillance System, as requested by IOM, is to record active surveillance information, especially once between days 21-28 of vaccination. Link between this system and the PVS is the PVN.

The Web site contains old forms and does not contain the Household Contact sheet. Has there been a change to PVS so that the Medical History will not be able to print the forms. Downloadable version is 4 pages and PVS is 2. Do we need to mass print PDF and distribute to clinics? What is available from PVS? (1/27/03)
The forms have been updated. It is preferable to use the downloadable forms, since the PVS system will not have the current forms. The last page of this downloadable form is a form that can be printed from the PVS system. It provides clinic and vaccine lot number.

What is the status of the PVS system? Please send the URL. (1/27/03)
A testing and training system is available on the internet, external to CDC. The production system is ready, but can only be accessed by a site once the site's digital certificate is confirmed. URL for test system will be sent to the person identified in the

data management section with a specific user id and password for the system. Any other questions can be sent to pvsinfo@cdc.gov

Is the PVS system going to generate the patient medical history consent form? (1/27/03)
No. This form will not be produced out of PVS anymore. What will be produced instead is a form with the clinical information block on it, which can be filled out by the clinician. They can then cut and paste this section of the form or copy it into the patient's record.

What is the Hospital Computer System? (1/24/03)
This is a tool that may assist hospitals with post-vaccination monitoring of their employees. This will enable hospitals to record data on site care monitoring, take checks, and active surveillance of adverse events. It will link to VAERS to report significant adverse events. The vision is to allow people to collect takes, monitor the sites, and conduct an interview during days 21-28, without re-entry in PVS. (Washington State has developed a similar system.) It is expected that this system will have the capability to link to PVS or the hospital's own system for take readings and follow-up. This system is not ready to go yet and won't be for a period of time.

Who is the contact for obtaining digital certificates at the state level? (1/24/03)
Vicki Kipreos can answer these questions. (vck5@cdc.gov)

Is the 'Campaign to Increase Physician Awareness about Smallpox and the Smallpox Vaccination Program' Packet ready yet? What changes are being made? What is the timeline? (1/24/03)
CDC is working on this right now. The final version is at least 3 weeks away. For mailing of this packet, 20 states prefer that these be mailed to the states in a collated fashion, so they can insert their own information. 9 states preferred that this be sent directly to the physicians on their behalf. States can contact Lynne Steele with the mailing information for their states (lvs6@cdc.gov).

How can states get the 11 minute videos? (1/22/03)
Claire Hannon sent out a note asking the states to identify the number of videos they needed. Claire polled members to determine the total number of videos to order.

Has CDC approved the ACIP recommendations? (1/22/03)
Yes, on 0/31/03.

Are the clinicians who attend AE training, the ones who request the VIG? *(1/15/03)*
Any clinician who is treating a patient with a smallpox AE can request the VIG. CDC requested that each state send their AE Coordinator and one state-selected clinician to attend the training on 1/22 and 1/23.

Are security protocols already issued for guarding of vaccine? *(1/17/03)*
CDC expects the states to keep the vaccine safe and secure, as any other vaccine following the Code of Federal Regulations. Smallpox vaccine must be stored in fixed storage facilities with controlled access to both the facility and storage system with surveillance and/or security staff provided. Armed guards on constant duty at the storage facility are not expected. Once vaccine is distributed to the dispensing clinics, the same precautions for the protection of any vaccine should be used.

NPS is under the assumption that states will order their vaccine all at once. This may not be the case for states that wish to vaccinate their vaccinators first, and the rest of their vaccinees later. *(1/17/03)*
CDC will ship up to 10,000 doses (100 vials) to each state initially and then follow-up with the remaining doses in one or more additional shipments.

Are people who have never been vaccinated against smallpox excluded from Stage 1 vaccination? *(1/15/03)*
No

What is the federal guidance on transportation of moderate risk samples?
In the current pre-event situation, "moderate risk" specimens should be transported according to the clinical diagnostic packaging and shipping requirements. Any specimen deemed to be "high risk" requires that both the CDC and appropriate law enforcement personnel be notified for collection and transportation.

Our state just received our CDC select agent registration in Nov, 2002. Are we required under 42CFR 73 to re-apply immediately?
The new regulations take effect on Feb. 7, 2003 with an application submission deadline of March 12, 2003. The new application forms are not yet available.

Is it necessary for the AE management training to be held on-site at CDC or can it be done via satellite broadcast? *(1/08/2003)*
CDC feels that the staff needs to be on-site for this training.

What is the job description and responsibilities for an AE Coordinator? *(1/08/2003)*
CDC outlined the description and responsibilities for an AE Coordinator in the pre-event guidance document and also requested that the states identify a coordinator in their plans. The coordinators are expected to know all aspects of AE monitoring and are able to link to the clinician when necessary.

What is the name of the contractor who can provide hotline services for the states?
For physicians: Logistics Health Inc., 1-877-554-4625
For public: American Social Health Association, 1-888-246-2675

Are lab workers considered part of the health care response teams? *(1/13/2003)*
The lab workers included in vaccinia diagnostics would be considered part the Public Health response teams, and should be included in the state vaccination team plans.

Is there a specific timeframe to return changes to the pre-event plan? Referring to changes not required to receive vaccine. *(01/13/2003)*
Send changes to the BT Project Officer. Report any significant updates to Project Officer.

Who should we contact to inform CDC that we have moved back the start date for vaccinations? *(1/13/2003)*
Contact the BT Project Officer.

When can CSTE expect the next update for Qs and As? *(1/13/2003)*
January 21.

What is the discipline of the AE Coordinators? *(1/06/2003)*
Mixed, however, there are a large number of physicians.

What is the schedule for the 1/22-23 AE Training Class? Should participants come in the night before and what time will the sessions end on 1/23? *(1/06/2003)*
Invitations to this class were sent out during the week of 1/6/03. Class is two full days and will require participants to travel on 1/21 and after 5 pm on 1/23.

Will travel costs be taken out of the BT grant or will CDC pay for travel? *(1/06/2003)*
CDC will pay travel costs for two participants.

How will the AE training provided by CDC relate to the training provided by the states? *(1/06/2003)*
States are encouraged to customize the materials provided by CDC for local training sessions.

Who within the states will receive the invitation to attend the AE Coordinator Training and will a contractor be used? *(1/06/2003)*
The invitations went to the AE Coordinator listed on the state's pre-event plan. Yes, a contractor will be used.

Is remote training an option? *(1/06/2003)*
It is not feasible to offer remote training for the AE Coordinator session. The agenda requires two full days, and also we would like the coordinators to network with other state coordinators.

For those who cannot attend, are there plans to make the training available via CD, the Internet or tape? *(1/06/2003)*
We will consider this option. Materials from the class will be available.

Can we drop the word "daily" from the AE site monitoring information? *(1/06/2003)*
Yes.

Has the Informed Consent document been finalized? If no, when? *(1/06/2003)*
The Informed Consent document was finalized and sent out to BT grantees on January 18.

Is it feasible for the states to have a home depot for VIG? *(1/06/2003)*
No; VIG will be at multiple CDC sites but there is a limited supply of VIG.

If a hospital worker is not willing to be vaccinated, can he/she still be a member of the response team? (Vaccination required on Consent Form.) *(1/06/2003)*
CDC would prefer members of the response teams to be vaccinated prior to a smallpox event, but will reconsider the issue.

Liability and Section 304 of the Homeland Security Act:
Is the use of VIG/Cidofovir covered in the liability provisions in Section 304? (1/27/03)
These are covered according to the declaration.

What is the indemnification for physicians who will be responsible for vaccine administration? (1/27/03)
Section 304 covers liability coverage, but does not address indemnity for adverse events.

Are security concerns a recognized reason to refuse a FOIA request? *(1/10/2003)*
Federal FOIA statutes only apply to records maintained at federal agencies and states have established their own rules and regulations on the release of data. States can review the federal guidelines for release of data that may have security concerns by going to: www.usdoj.gov At the website, go to "FOIA" in the left column, then to "Reference Materials". In the references materials link to "DOJ FOIA Guide". In the DOJ FOIA Guide Table of Contents click on "Exemption 2-High 2".

If vaccine administration differs from what is stated in the package insert (e.g. 3 vs 15 sticks) will liability still be covered under Section 304 of the Homeland Security Act? *(1/10/2003)*
CDC and others are currently in the process of submitting data to the FDA to support changing the recommendation of three needle sticks for primary vaccinations to 15 sticks for both primary and revaccination. It is important to note that during the smallpox eradication period, the World Health Organization (WHO) program used 15 needles sticks universally to avoid confusion and to help decrease the number of vaccine take failures from flaws in vaccine administration techniques. However, until the FDA approves a package insert change, vaccinators should follow the instruction found on the vaccine package insert on the number of needle sticks to administer for primary vaccines and revaccinees.

Has CDC issued guidelines about what level of security it expects for smallpox vaccine? Should there, for example, be a guard posted 24/7 at the main storage facility, or are electronic monitors and locked "layers" (building, room, refrigerator)

sufficient? Once vaccine is distributed to dispensing clinics, are there different standards for security? *(1/10/2003)*
CDC expects the states to keep the vaccine safe and secure, as any other vaccine, following the Code of Federal Regulations. Smallpox vaccine must be stored in fixed storage facilities with controlled access to both the facility and storage system with surveillance and/or security staff provided. Armed guards on constant duty at the storage facility are not expected. Once vaccine is distributed to the dispensing clinics, the same precautions for protecting at any vaccine should be used.

Compensation:

How is CT dealing with the compensation issues? (1/22/03)
CT legislation requires health insurers to cover the cost of hospitalization for all health workers. Also workman's compensation will cover the workers. Others vaccinated are considered state employees for the purpose of Stage I and covered by State insurance. Anyone involved in the transmission of vaccinia is free of liability.

Miscellaneous:
What is the process of communication between military installations and the local/state health departments? (1/29/03)
The public notice of military smallpox vaccination has been out since 12/13/02, so state and local health departments with nearby military installation can expect to have vaccinated military personnel in their state. The installations' preventive-medicine/public-health departments will be reminded to call the state health department, but given the current increased demands on the military the communications bridge needs to operate in both directions.

How do military personnel who may happen to be treated at civilian hospitals get access to VIG? (1/29/03)
For DoD beneficiaries and families of Reserve Component personnel, DoD will work diligently with civilian institutions to assist. This could involve moving the patient to a military hospital or arranging for VIG at the civilian hospital. Physicians treating personnel vaccinated through the DOD can obtain VIG through the DOD system after completing documents required by the FDA. An employee vaccinated through the hospital's program who requires VIG would probably obtain it through the CDC, even if he or she was a Reservist or in the National Guard.

How do civilian physicians treating military vaccinees access VIG? (1/29/03)
Civilian physicians can begin the process of requesting VIG according to instructions at the DOD website at www.smallpox.army.mil/resource/pdf/PRTemplate.pdf <http://www.smallpox.army.mil/resource/pdf/PRTemplate.pdf>
Civilian physicians who first call the CDC hotline will be provided the information they need.

Are the Monday, Wednesday, Friday calls enough? Should these be expanded to occur every day? (1/29/03)
For now, we will continue with the M-W-F frequency.

Hospitals are interested in data regarding individuals who have already been vaccinated, and how those vaccinations are going (e.g., military updates and Israeli vaccination information would be useful). (1/27/03)
DoD has been very accommodating in this arena, and will try to attend the call as much as possible (once a week?). DoD cannot provide the total number of vaccinees for security reasons but will help with as much information as possible.

Is there any new information on the Israeli vaccination? (1/22/03)
They have vaccinated over 18,000. No other new information.

Connecticut (CT) will vaccinate the vaccinators and Public Health Staff, and then wait until 2/10 to vaccinate the health care workers. Why is CT waiting 2.5 weeks to start vaccinating health care workers? Is there anything significant about 2.5 weeks? (1/22/03)
CT decided to wait 2.5 weeks to ensure that the vaccinators are not having any adverse effects from the vaccine.

How will the states know when the reservists are vaccinated? *(01/17/03)*
DoD will provide general information to the states but cannot post when the vaccinations will be taking place.

Are family members of military vaccinees going to be cared for in public hospitals? Should the public hospitals access CDC information or the military systems? *(01/17/03)*
Factors to consider:
- Active Duty members are covered and their families are as well.
- Guard members and reservists are covered by military but their families are not.
- Military clinics may not be open 24 hours a day for all military-related personnel.

If a DoD vaccinee needed VIG, regardless of their affiliation to a military member, the military will take as much responsibility as possible. This may warrant movement of a civilian family member to a military hospital, or movement from a military hospital to a civilian hospital.
The military website details this support information, including their 24 hour hotline. 301-619-2257 or 888-USA-RRID

Is it true that all vaccinations of military personnel will occur on installations? *(01/17/03)*
It should be but there are some private sector contracts that may require isolated vaccinations on private ground. It is conceivable that vaccinations will be occurring at places other than major bases.

What has been the military adverse event experience? *(01/17/03)*
Everything has been expected and temporary. Of ~700 vaccinees, general malaise has been experienced, 1 patient developed a general rash; and restriction of duty: 3% for primary vaccinees, 1.5% for repeat vaccinees. This has been shared with CDC and IOM.

Will CDC release the names of the states receiving vaccine? *(01/17/03)*
CDC will post the number of doses that a state has been shipped after the state acknowledges receipt. (See http://www.cdc.gov/od/oc/media/smallpox.htm)

What specific information should public health tell hospitals about the military vaccination program for reservists? *(1/15/03)*
The local health department should tell the area hospitals that patients presenting with adverse events after vaccinations are a possibility. If this situation occurs, the hospital should treat the person and contact the military for billing and CDC website for guidance.

Has the guidance for Stage II been put on hold? *(01/10/2003)*
Stage II guidance is not on hold, it is simply not finished.

Will there be military medical personnel (Reservists or Active Duty) who are vaccinated during their military training but who return to (or moonlight in) civilian hospitals before the vaccination site is healed? If so, will any of these medical personnel be vaccinated before Jan. 24? *(01/10/2003)*
Yes, there may be medical personnel vaccinated as part of the DOD program who will be working in civilian hospitals before the vaccination site is healed.
A few of these medical personnel may be vaccinated before January 24.
Vaccinated military personnel have been instructed to notify their civilian hospital employers.

Are there military personnel receiving both the anthrax vaccinations and the smallpox vaccination around the same time? *(01/10/2003)*
DOD protocol is that it is preferable to separate the vaccinations. However, all vaccinations may be combined, according to ACIP recommendations, if the timing for deployments does not allow for separation.

How do military personnel who may happen to be treated at civilian hospitals get access to VIG? *(01/10/2003)*
For DOD beneficiaries and families of Reserve Component personnel, DOD will work diligently with civilian institutions to assist. This could involve moving the patient to a military hospital or arranging for VIG at the civilian hospital. Physicians treating personnel vaccinated through the DOD can obtain VIG through the DOD system after completing documents required by the FDA. An employee vaccinated through the civilian hospital's program who requires VIG would probably obtain it through the CDC, even if he/she were a Reservist or in the National Guard.

How do civilian doctors treating military vaccinees access VIG? *(01/10/2003)*

Civilian doctors can begin the process of requesting VIG according to instructions at the DOD website at: www.smallpox.army.mil/resource/pdf/PRTemplate.pdf
Civilian physicians who first call the CDC hotline will be provided the information they need.

What is the CDC collaboration with WHO?
The CDC historically and currently works closely with the WHO in the evaluation and investigation of possible cases of smallpox. The poxvirus laboratory at the CDC is one of two WHO reference laboratories for the evaluation of smallpox and other human pathogenic poxviruses.

Is the military going to be using VAERS for AE reporting? *(01/10/2003)*
Yes.

What is the correlation between ACIP, CDC and FDA in respect to smallpox vaccination?
FDA is a federal agency in the Department of Health and Human Services (DHHS) responsible for licensing products based on information received from studies conducted by the manufacturer.
CDC is a federal agency in DHHS that is responsible for the implementation of federal vaccination programs and with the FDA monitors their safety.
The ACIP is an Advisory Committee to DHHS that deliberates and then provides recommendations on the effective control of vaccine preventable diseases in the civilian population.